REMARKS OF CONGRESSMAN HENRY A. WAXMAN

TO FURMAN SELZ MAGER DIETZ AND BIRNEY

FEBRUARY 6, 1990

I am pleased to have the opportunity to speak with you today. As Chairman of the Subcommittee on Health and the Environment, I have the opportunity to address a wide range of health issues, but few are more important than the issues pertaining to the safety and prices of prescription drugs.

During recent years, the Subcommittee has held hearings on the cost of prescription drugs; we have looked at the impact of drug prices on the federal budget; we have enacted legislation promoting competition and extending the patents given to new drug discoveries; and in the future we are likely to be drawn into the debate about the circumstances under which companies should be permitted to advertise prescription drugs to consumers. We also are vitally interested in whether the FDA is scrupulously enforcing the safety and efficacy requirements of the Federal, Food, Drug and Cosmetic Act.

Prior to 1984, the Food and Drug Administration had a patchwork policy toward generic drugs. Once the patent on a drug had expired, Abbreviated New Drug Applications (or "ANDAs") were permitted for drugs first approved prior to 1962, but not for drugs first approved after

that year. Thus, a company that wished to market a copy of a pre-1962 drug did not have to conduct tests to show that the product was safe and effective. That had already been demonstrated by the pioneer company.

Instead all that was required was that the company show that it could make a good copy of the pioneer drug -- that its drug was interchangeable with the pioneer. This often involves studies to show that the drug is absorbed into the bloodstream at approximately the same rate as the pioneer.

For reasons that I have never been able to understand, drugs that were first approved after 1962 were not eligible for ANDA. This policy was not a problem during the 1960's and most of the 1970's because most of the post-1962 drugs were protected by patents. Generic companies were legally barred from marketing competing products.

By the early 1980's, there was increasing interest on the part of generic companies in marketing copies of post-1962 drugs. Although the FDA dispensed with the full testing requirements where there was published literature to support safety and effectiveness, it prohibited generic competition for many important drugs that had come off patent; and it was clear that it would do so in the future for many others that were about to lose their patent protection.

The FDA's approach was a bad public policy for two reasons. First, it barred the marketing of many generic drugs. This loss of competition resulted in artificial, monopoly pricing long after the patent on the pioneer drug had expired. As a result, consumers paid too much for prescription drugs; not insignificantly, so did the federal government.

Second, the FDA's approach resulted in the unnecessary expenditure of testing and regulatory resources. Under the FDA's policy, companies that wanted to market generic drugs for post-1962 products were required to redo all the clinical studies necessary to demonstrate that the drug was safe and effective. The FDA, which had already found that the pioneer's product met the standards of the Act, was required to review this data and to reach a conclusion as though it were evaluating the issue for the first time. This entire exercise seemed to me to involve a ridiculous expenditure of research resources, as well as regulatory resources on the part of the Food and Drug Administration.

When the Reagan Administration made it clear that it would not adopt a post-1962 generic drug policy, I introduced legislation to require the FDA to extend its ANDA policy to any drug that had lost patent protection. The bill would have required the FDA to approve generic drugs as long as the applicant demonstrated that it could make a good copy of the pioneer product.

At that time, Senator Hatch was sponsoring a bill to extend the patents for drugs that had lost patent time because of the FDA regulatory review process. My bill had support from consumer groups and the generic drug companies, but was opposed by the trade-name prescription drug companies. These groups flipped sides when it came to Senator Hatch's patent-term extension bill. We combined our bills and enacted them as the Drug Price Competition Act and Patent Term Restoration Act of 1984, also affectionately, and not-so-affectionately, known as the "Waxman-Hatch" law.

The Act has been a tremendous success in terms of stimulating competition for prescription drugs. Since 1984, the FDA has approved about 3,000 generic drugs, almost as many as it had approved during its entire prior history.

In 1984, generic drug sales were between $500 million and $1 billion. Estimates are that by 1988, the sales had increased about 7 times, to between $3.4 and $7 billion.

The American Association of Retired Persons, which runs a very successful mail order pharmacy, reports that generic drug prescription prices are typically 30% to 50% below the price of the brand name product, and that approximately 80% of prescription drugs are available in their generic form.

That is the good news. The bad news is that, as everyone in this room well knows, both the Food and Drug Administration and the generic drug industry have experienced some very hard times during the past year. Three FDA employees in the agency's generic drug division accepted illegal gratuities, which is a nice way of saying that they took bribes. A number of other companies have been caught submitting fraudulent data to the FDA. In some instances, a company that wanted to satisfy the requirement to show that it could make a good copy simply submitted a sample of the pioneer product to the agency. This is fraud that completely undermines the public health protections of the law.

To make matters worse, the Agency did not discover these problems on its own. It took a Congressional investigation by Congressman John Dingell, Chairman of the Committee on Energy and Commerce, of which my subcommittee is a part.

Fortunately, neither the FDA nor Congressman Dingell's investigation has identified any significant safety problems with generic drugs. The FDA officials were bribed so that a company could get an early approval, but the products being sold were safe, as far as we know.

But the public's confidence in the FDA and in generic drugs has been shattered. To make matters more difficult, generic drugs are

marketed simply as "generics." Most people cannot identify a single generic company, unless they recall reading about a company that has been a subject of the recent investigation. Nor do consumers know the brand-name of the generic drugs that they use. In contrast, consumers do recognize the names of prescription drug companies and the brand names they sell.

Take the example of Oraflex, Eli Lilly's anti-arthritic product. When Lilly was convicted of criminal wrongdoing for failing to submit critical data in connection with its application to market Oraflex, the public did not question all pioneer products. Instead, consumers associated the bad publicity with a particular product and a particular company.

In the case of generic drugs, the entire industry has had to suffer the consequences of wrongdoing by a very small percentage of generic companies. The press is partially responsible for this, since it treated Congressman Dingell's investigation as an indictment of the entire generic industry. But this phenomenon is also attributable to the way that generic drugs have been marketed.

Why did generic drug companies get in so much trouble? I don't think anybody really knows the answer to that question. I have thought about it and I am convinced that the underlying problem is not the 1984 law.

The purpose of the 1984 Act was to set the standards under which generic drugs would be available, and we adopted the general approach that the FDA had previously employed. To my knowledge, no one has identified any fundamental problem with the standard requiring generic companies to demonstrate that they can make a good copy of the brand name product. Certainly, the problem is not that the law removed the artificial barriers from marketing generic drugs. Instead, the problem was old fashioned fraud.

While I don't have the full answer to the question of why so many generic drug companies were able to break the law without being caught by the FDA, I do believe that the FDA's approach to law enforcement, particularly during the Reagan Administration, was an important factor. Early in that administration, the FDA began bringing fewer criminal prosecutions and other law enforcement actions. It cut back the resources that it was devoting to enforcement, and instead started talking about "voluntary" industry regulation. Wherever possible, it tried to accommodate rather than to regulate. Indeed, in the early 1980's, the FDA brought about one-half the law enforcement actions that the agency had brought during the Carter Administration.

The 1984 Act was enacted in the midst of this lax enforcement climate. It opened the door to enormous profits to companies that had not participated in the FDA regulatory process. Since the first generic company to get on the market stood to gain a highly profitable

advantage, perhaps the FDA should have anticipated that some companies would choose to cut illegal corners. But since it was in a deregulatory mode, it did not anticipate. And the result is a mess for the entire generic drug industry.

The Congressional investigation has strengthened interest in oversight of the Food and Drug Administration, and I doubt that Congress's interest will be limited to generic drugs. There are also serious problems with the regulation of medical devices, the non-regulation of cosmetics and the delays in reviewing over-the-counter drugs for safety and efficacy. I am not talking about criminal fraud, but simply lax regulation and inadequate enforcement of the law.

It is still too early to say what form any legislation will take. Congressman Dingell has indicated that he will seriously consider legislative reform. In addition, the Administration has announced that it will form a commission to make recommendations. The Pharmaceutical Manufacturers will announce their recommendations shortly and the Generic Pharmaceutical Industry Association is in the process of forming a Commission of its own to do the same.

I don't know where we will end up. I am confident that serious thought will be given to beefing up the FDA's law enforcement capabilities. The agency also needs to adopt regulations to insure as much as possible that there will be no more generic drug scandals. If

it doesn't act, Congress is likely to give it firm direction.

These are hard times for the generic drug industry and the FDA. I am confident that generic drugs will continue to be a very important element of our health care system. Hopefully, the FDA will emerge from the current investigation as a stronger agency. Hopefully, it will be able to regain the public's confidence. If it does, the future will be bright for the generic drug industry.

Thank you. I would be happy to answer any questions.